

Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-EE64BD1F-6B2A-4653-9F73-21E8F4E01D26_2_en-US
DOI: https://doi.org/10.31003/USPNF_M28730_02_01
DOI Ref: 25ivf

© 2025 USPC
Do not distribute

Dydrogesterone Tablets

» Dydrogesterone Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{21}H_{28}O_2$.

Packaging and storage—Preserve in well-closed containers.

USP REFERENCE STANDARDS (11)—

[USP Dydrogesterone RS](#)

Identification—Extract a quantity of the powdered Tablets, containing about 60 mg of Dydrogesterone, with 20 mL of methanol, filter, and evaporate to dryness: the residue so obtained responds to [Identification](#) test [A](#) under [Dydrogesterone](#).

DISSOLUTION (711)—

Medium: 0.3% sodium lauryl sulfate; 500 mL.

Apparatus 2: 100 rpm.

Time: 60 minutes.

Procedure—Determine the amount of $C_{21}H_{28}O_2$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 295 nm of filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of [USP Dydrogesterone RS](#) in the same medium.

Tolerances—Not less than 75% (Q) of the labeled amount of $C_{21}H_{28}O_2$ is dissolved in 60 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

Assay—

Mobile phase, Standard preparation, System suitability preparation, and Chromatographic system—Proceed as directed in the [Assay](#) under [Dydrogesterone](#).

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer a portion of the powder, equivalent to about 20 mg of Dydrogesterone, to a 200-mL volumetric flask, add about 100 mL of *Mobile phase*, and sonicate for 10 minutes. Cool to room temperature, dilute with *Mobile phase* to volume, and mix.

Procedure—Separately inject equal volumes (about 20 μ L) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and determine the peak responses by area measurement. Calculate the quantity, in mg, of $C_{21}H_{28}O_2$ in the portion of Tablets taken by the formula:

$$200C(r_u/r_s)$$

in which C is the concentration, in mg per mL, of [USP Dydrogesterone RS](#) in the *Standard preparation*, and r_u and r_s are the Dydrogesterone peak area responses from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DYDROGESTERONE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 50(2)

Current DocID: GUID-EE64BD1F-6B2A-4653-9F73-21E8F4E01D26_2_en-US

Previous DocID: GUID-EE64BD1F-6B2A-4653-9F73-21E8F4E01D26_1_en-US

DOI: https://doi.org/10.31003/USPNF_M28730_02_01

DOI ref: [25ivf](#)

OFFICIAL